Attorney Docket No. 56876 (45579)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	K. Osther et al.	**EXAMINER:**	Miller, Cheryl L.
U.S.S.N.:	10/057,112	**GROUP:**	3738
FILED:	January 25, 2002	**CONF. NO.:**	1887
FOR:	IN VITRO REPAIR OF BONE AND/OR CARTILAGE DEFECTS		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION UNDER 37 CFR §1.132

Dear Sir:

We, Kurt OSTHER a resident of the United States and Peter STORGAARD a resident of Denmark, declare and say that We are co-inventors of claims 29-33, 39-42 and 52 in the above-identified application (hereinafter "Application"). We personally performed and/or assisted in research leading to the invention.

We have recently read the Application and the Office Actions mailed April 14, 2004 and July 2, 2004 and (collectively "Office Action") issued in the Application. As We understand it, claims 29-33 and 52 were rejected as being anticipated by U.S. Patent No.5,759,190 (Vibe-Hansen); claims 29, 31, 32, and 52 were rejected as being anticipated by U.S. Patent No. 5,876,452 (Athanasiou); claims 29, 31-33, and 52 were rejected under 35 U.S.C. § 102 (e) as being anticipated by U.S. Patent No. 6,080,194 (Pechence). Claims 29-33, 39-42, and 52 are rejected under 35 U.S.C. § 102 (e) as being anticipated by U.S. Patent No. 6,251,143 (Schwartz).

We state that Vibe-Hansen's use of Tissel (Col. 3, line 25-28 and col. 6, lines 45-55) does not have the same function as the stimulation molecule in our invention. Tissel is said to contain fibronectin and fibrinogen, among other components. (Col. 6, lines 52-55). In the Office Action, the Examiner asserts that

because Tisseel contains fibronectin and fibrinogen, it must inherently have the same function as a stimulation molecule in our invention. This has been proven *not* to be the case by Mats Brittberg et al. in an article entitled, "The influence of fibrin sealant (Tisseel®) on osteochondral defect repair in the rabbit knee," which was published in the journal Biomaterials, Vol. 18 (3) (1997) pp. 235-242 and is attached here as Exhibit A. The authors concluded, "...a fibrin adhesive like Tisseel® is not suitable as a scaffold to promote repair of osteochondral defects in the rabbit knee." (emphasis added). Although Tisseel contains fibronectin and fibrinogen. We state that the mere presence of these components cannot induce signal transduction or act as a stimulation molecule as required by our invention.

We state that our invention is a cell-free cartilage membrane (implant) and kit comprising at least one surface part carrying a composition comprising at least one stimulation molecule, which is selected from collagen proteins, proteoglycans and non-collagenous proteins.

We state that Pachence nowhere discloses a stimulation molecule as required by the claims. Thus, we believe that Pachence cannot anticipate the claims because Pachence does not teach or suggest each and every element of the claims.

We state that the Schwartz reference does not describe the claimed cartilage membrane. Instead, Schwartz et al., describe a bio-absorbable assembly system composed of a delivery unit and a porous insert. Our claimed system is only a membrane and therefore is different. The insert of Schwartz is supported by a delivery system unit, formed of bio-absorbable material, and is used to establish communication between the removed area (damaged cartilage) and an adjacent healthy cartilage and bone area, as a chondrogenic growth supporting matrix. As we understand it Schwartz is different from our invention, which describe a cartilage repair system composed of a stimulating membrane implanted. Thus, we believe that Schwartz cannot anticipate the claims because Schwartz does not teach or suggest each and every element of the claims.

We hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title XVIII of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Peter Storgaard

Date: 15. October 2004

Kurt Osther

Date: 15. October, 2004